K012572/S1
page 1 of 2

DEC 0 3 2001

BIOMET
CORPORATE HEADQUARTERS

# SUMMMARY OF SAFETY AND EFFECTIVENESS

**Applicant or Sponsor:**

Arthrotek, Inc.
(A wholly owned subsidiary of Biomet, Inc.)
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0578
Establishment Registration No.:1825034

**Contact Person:**

Sara B. Shultz
Biomet Manufacturing, Corp.
P.O. Box 587
Warsaw, Indiana 46581-0578
Phone: (219) 267-6639
FAX: (219) 372-1683

**Proprietary Name:** Soft Tissue Screw and Washer

**Common or Usual Name:** resorbable screw and washer

**Classification Name:** Fastener, Fixation, Biodegradable soft tissue

**Device Product Code:** 87MAI

**Legally Marketed Devices To Which Substantial Equivalence is Claimed:**
Mini Harpoon® Suture Anchor (Biomet, Inc., K973775), Acufex's Suretac® (Acufex, K931519), Resorbable Bone Pin (Biomet, Inc., K011522), Mitek GII Anchor (Mitek Surgical Products, Inc., K953877), Quick Anchor Plus (Mitek Surgical Products, Inc., 510(k) number unknown).

**Indications for Screw and Washer:**
Shoulder Indications: Bankart repair, SLAP lesion repair, acromioclavicular separation repair, rotator cuff repair, capsule repair and capsulolabral reconstruction, biceps tenodesis, deltoid repair.

Wrist Indications: Scapholunate ligament reconstruction.

Elbow Indications: Tennis elbow repair, biceps tendon reattachment, medial and lateral repairs, ulnar or radial collateral ligament reconstruction.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE 219.267.6639 ■ FAX 219.267.8137 ■ E-MAIL biomet@biomet.com

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Knee Indications: Extra-capsular repair: Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tenodesis reconstruction, patellar ligament/tendon repair, vastus medialis obliquus (VMO) muscle advancement.

This product is preloaded with suture for use at the discretion of the physician.

**Device Description:** The device is a resorbable screw and washer assembly. The screw measures 12.5mm in length and 2.25mm in diameter. The washer is oval shaped and measures 7mm along the long axis with two spikes to hold the soft tissue in place. The device is fully cannulated to accommodate the driver mechanism. The device may be used with any legally marketed suture (size 1 or 2) for secondary reattachment of soft tissue.

**Summary of Technologies:** The Soft Tissue Screw and Washer technological characteristics (material and design) are similar to the predicate devices.

**Non-Clinical Testing:** Mechanical testing was performed to establish substantial equivalence to the predicate devices.

**Clinical Testing:** Clinical testing was not used to establish substantial equivalence to predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 3 2001

Ms. Sara B. Shultz
Regulatory Specialist
Biomet, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581

Re: K012572
Trade/Device Name: Soft Tissue Screw and Washer
Regulation Number: 888.3040, 888.3030
Regulation Name: Smooth or threaded metallic bone fixation fastener
Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HWC, HTN
Dated: October 24, 2001
Received: October 25, 2001

Dear Ms. Shultz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012572 S1



510(k) NUMBER (IF KNOWN): K012572

DEVICE NAME: Soft Tissue Screw and Washer

INDICATIONS FOR USE:

**Indications for Screw and Washer:**

Shoulder Indications: Bankart repair, SLAP lesion repair, acromioclavicular separation repair, rotator cuff repair, capsule repair and capsulolabral reconstruction, biceps tenodesis, deltoid repair.

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Knee Indications: Extra-capsular repair: Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tenodesis reconstruction, patellar ligament/tendon repair, vastus medialis obliquus (VMO) muscle advancement.

The Soft Tissue Screw and Washer is preloaded with suture for use at the discretion of the physician.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1-2-96)

for Mark N. Milhous

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012572